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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/801,287  | 03/16/2004  | Johann Karl Kitta    | KITTA ET AL.-1      | 3043             |
| 25889   | 7590        | 07/09/2007           | EXAMINER            |                  |
| WILLIAM COLLARD<br>COLLARD & ROE, P.C.<br>1077 NORTHERN BOULEVARD<br>ROSLYN, NY 11576 |             |                      | TOWA, RENE T        |                  |
|   |             | ART UNIT             |                     | PAPER NUMBER     |
|   |             | 3736                 |                     |                  |
|   |             | MAIL DATE            | DELIVERY MODE       |                  |
|   |             | 07/09/2007           | PAPER               |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

WA

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/801,287             | KITTA ET AL.        |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Rene Towa              | 3736                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 07 June 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-7,9-11,14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-7,9-11,14 and 15 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

|   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date: _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/9/07</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

***DETAILED ACTION***

1. This Office action is responsive to an amendment filed June 7, 2007. Claims 1-7, 9-11 and 14-15 are pending. Claims 8 & 12-13 are cancelled. No new claim has been added.

***Claim Rejections - 35 USC § 103***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al (US Patent No. 5,769,826) in view of Collins (US 1,640,481).

In regards to claim 1, Johnson et al. discloses a hollow needle holder comprising:

(a) a hollow needle container (10) having an inside and an outside (Figure 1) and first face comprising a closable opening and a second face (see figure 1);

(b) a hollow needle fixing device (30, 32) disposed from the inside of the hollow needle container (Figure 1) on said second face for receipt of a hollow needle (42) or an adapter for a hollow needle attachable to the hollow needle fixing device from the outside through an opening 17 in the second face of the hollow needle container (Figure 1) and projecting through said hollow needle fixing device (30, 32) into said hollow needle container;

(c) an unlocking mechanism (70 & 72) for releasing the hollow needle or adapter after use so that the hollow needle fixing device (30, 32) together with the hollow

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needle or adapter falls into said hollow needle container after activation of said unlocking mechanism (see figure 2); and,

(d) a closure device (20, 80) for closing said hollow needle container (10) (see figs. 1-2, 5 & 7).

In regards to claim 2, Johnson et al. discloses a hollow needle holder, further comprising an anchoring device (31, 73) releasably fixing said hollow needle fixing device in place on said hollow needle holder (see figs 2-3).

*Johnson et al. disclose an apparatus wherein the slot 73 cooperates with the needle carrier 30, 32 via groove 31 to releasably hold the needle carrier in place until activation (see column 3/lines 15-23 & 34-36).*

In regards to claim 3, Johnson et al. discloses a hollow needle holder, wherein said hollow needle fixing device (30) is engageable on the hollow needle holder (see figures 1 & 2).

In regards to claim 4, Johnson et al. discloses a hollow needle holder, wherein the hollow needle holder has a passage opening (100) for the hollow needle or the adapter and at least one attachment opening (17) for said hollow needle fixing device on said second face (see figs. 1-2).

Johnson et al. disclose an apparatus, as described above, that teaches all the limitations of the claims except Johnson et al. do not explicitly teach an apparatus wherein the closure device includes a sliding mechanism.

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However, Collins discloses an apparatus comprising a closure that includes a slide 10 (see figs. 1-8; column 1/lines 8-14 & 19-28).

Applying the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) and are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an apparatus similar to that of Johnson et al. with a closure device similar to that of Collins in order to provide a sanitary closure which will securely seal the contents of the container and prevent leakage (see Collins, column 1/lines 8-14).

Johnson et al. as modified by Collins, above, fail to disclose an apparatus wherein the unlocking mechanism includes a closure device. Instead Johnson et al. as modified by Collins teach an apparatus that includes a locking mechanism separate from a closure device.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide a locking mechanism with a closure device because the Applicant has not disclosed that having the locking mechanism integral with the closure device provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art,

furthermore, would have expected Johnson et al. as modified by Collins's apparatus and Applicant's invention to have performed equally well with either the separate locking mechanism and closure device taught by Johnson et al. as modified by Collins or the claimed integral locking mechanism with a closure device because both would perform the same function of releasably locking the hollow needle or adapter and sealing the second face of the apparatus (see Johnson et al., column 3/lines 50-51; see Collins, column 1/lines 8-14).

Therefore, it would have been prima facie obvious to modify the apparatus of Johnson et al. as modified by Collins to obtain the invention as specified in claim 1 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Johnson et al. as modified by Collins.

Moreover, it has previously been held that merely making integral (i.e. the locking mechanism and the closure device) is not patentable--See *in re Larson*, 340 F. 2d 965, 967, 144 USPQ 347, 349 (CCPA 1965); *In re Wolfe*, 251 F.2d 854, 855, 116 USPQ 443, 444 (CCPA 1958).

4. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al ('826) in view of Collins ('481) further in view of Crawford et al. (US Patent No. 6,306,118).

Johnson et al. as modified by Collins disclose an apparatus, as described above, that teaches all the limitations of the claims except Johnson et al. as modified by Collins

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do not teach a hollow needle fixing device having at least one flexible arm having a wedge-shaped projection.

However, Crawford et al. disclose an apparatus including a hollow needle fixing device 500 having at least one flexible arm 528 having a wedge-shaped projection 530 (see figs. 1 & 9).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an apparatus similar to that of Crawford et al. with a needle fixing device having at least one flexible arm having a wedge-shaped projection similar to that of Crawford et al. in order to releasably secure the needle fixing device to the hollow needle container (see Crawford et al., column 6/lines 24-29; see figures 1-2).

5. Claims 6-7 & 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al ('826) in view of Collins ('481) further in view of Wanamaker et al. (US Patent No. 5,117,837).

Johnson et al. as modified by Collins disclose an apparatus, as described above, that teaches all the limitations of the claims except Johnson et al. as modified by Collins do not teach a locking mechanism having a second slide.

However, Wanamaker et al. disclose an apparatus including a locking mechanism having a second slide (700, 712) including a pair of guides (782, 784) engaging an anchoring device 800; wherein said second slide (700, 712) projects beyond an edge of a hollow needle container 200 (see figs. 1-2 & 7-9).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an apparatus similar to that of Johnson et al. as modified by Collins with a second slide similar to that of Wanamaker et al. since such a modification would amount to a design choice that would serve the same purpose of locking the hollow needle or adapter in place (see Wanamaker et al., see figs. 7-9).

6. Claims 6-7, 9-11 & 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al ('826) in view of Collins ('481) further in view of Fuji et al. (US 5,797,490).

Johnson et al. as modified by Collins disclose an apparatus, as described above, that teaches all the limitations of the claims except Johnson et al. as modified by Collins do not teach a locking mechanism having a second slide.

However, Fuji et al. disclose an apparatus including a locking mechanism having a pair of slides (22, 23) including a pair of guides (224, 248) engaging an anchoring device (213, 223); wherein said second slide (22, 23) projects beyond an edge of a hollow needle container 1; wherein the unlocking mechanism 2 has a cap 24 arranged to rotate on said hollow needle container 1, said slides (22, 23) being so that rotation of said cap 24 moves said slides (22, 23); wherein said cap 24 has a guide 248 and said slides (22, 23) has a guide element 224 said guide 248; wherein the apparatus further comprises a plug-in connector (213, 223) disposed in said hollow needle fixing device 2 for rotatably mounting said hollow needle or adapter (see figs. 1-18; column 1/lines 55-65; column 3/lines 8-21, 44-46 & 52-63; column 4/lines 10-17; column 5/lines 13-14, 18-20 & 22-24).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an apparatus similar to that of Johnson et al. as modified by Collins with a second slide similar to that of Wanamaker et al. since such a modification would amount to a design choice that would serve the same purpose of locking the hollow needle or adapter in place (see Wanamaker et al., see figs. 7-9).

Moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an apparatus similar to that of Johnson et al. as modified by Collins with a rotatable cap similar to that of Fuji et al. in order to provide an apparatus that is releasably attachable to a needle or adapter at any convenient unobstructed viewing angle of the user.

Even moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an apparatus similar to that of Johnson et al. as modified by Collins with a plug-in connector similar to that of Fuji et al. in order to threadingly releasably attach a needle or adapter.

7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al ('826) in view of Collins ('481) further in view of Chen (US 6,764,465).

Johnson et al. as modified by Collins disclose an apparatus, as described above, that teaches all the limitations of the claims except Johnson et al. as modified by Collins do not teach a needle fixing device arranged offset from a center axis of said hollow needle holder in a radial direction.

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However, Chen discloses an apparatus comprising a needle fixing device arranged offset from a center axis of said hollow needle holder in a radial direction (see fig. 7).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an apparatus similar to that of Johnson et al. as modified by Collins with a needle fixing device arranged offset from a center axis of said hollow needle holder in a radial direction similar to that of Chen since such a modification would serve the same purpose of releasably fixing the needle to the syringe barrel.

Moreover, it has previously been held that merely shifting location of parts is not patentable--See *In re Japikse*, 181 F. 2d 1019, 1023, 86 USPQ 70, 73 (CCPA 1950).

8. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al ('826) in view of Collins ('481) further in view of Ruetz (US 2,111,482).

Johnson et al. as modified by Collins disclose an apparatus, as described above, that teaches all the limitations of the claims except Johnson et al. as modified by Collins do not teach a slideable needle fixing device arranged offset from a center axis of said hollow needle holder in a radial direction.

However, Ruetz discloses an apparatus comprising a slideable device arranged offset from a center axis of said hollow needle holder in a radial direction (see figs. 1-2).

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It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide an apparatus similar to that of Johnson et al. as modified by Collins with a slideable device arranged offset from a center axis of said hollow needle holder in a radial direction similar to that of Ruetz since such a modification would serve the same purpose of releasably fixing the needle to the syringe barrel.

Moreover, it has previously been held that merely shifting location of parts is not patentable--See *In re Japikse*, 181 F. 2d 1019, 1023, 86 USPQ 70, 73 (CCPA 1950).

***Response to Arguments***

9. Applicant's arguments filed June 7, 2007 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RTT/

  
MAX F. HINDENBURG  
TELECOMMUNICATIONS PATENT EXAMINER  
TECHNOLOGY CENTER 2700